K101225

SECTION 2. SUMMARY AND CERTIFICATION

JAN 25 2011

A. 510(k) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Promimic AB summary for the ***Promimic Dental Implant.***

SUBMITTER'S NAME: Promimic AB

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Sweden

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DATE OF SUBMISSION: April 30, 2010

1. **Identification of device**
   Proprietary Name: Endosseous Implant and Abutment
   Common Name: ***Promimic Dental Implant***
   Classification Status: Class II per regulations 872.3640
   Product Codes: DZE

2. **Equivalent devices**
   Promimic AB believes the ***Promimic Dental Implant*** is substantially equivalent to:

K073161	Implant Direct Inc	Replus Dental Implants (HA)
K062432	Implant Innovation Inc	NanoTite Dental Implants
K925765	Nobelpharma USA Inc	Brånemark System Standard 3.75 mm Fixture
K991053	Astra Tech Inc	Astra Tech Implants- Dental system: New fixtures (micromacro)

3. **Description of the Device**
   The ***Promimic Dental Implant*** consists of 4 implants, diameter 3.75 mm, and length from 8.5 to 15.0 mm.

4. Intended use

The Promimic AB, ***Promimic Dental Implant*** is intended for surgical placement into the bone of upper /lower jaw arches as a permanent anchorage for prosthetic devices and to restore chewing function. The Promimic Dental Implant can be immediately loaded only with good primary stability and appropriate occlusal loading. The Promimic Dental Implants are only to be used with straight abutments.

Promimic Dental Implants are compatible with the following abutment system:

510(k) K910611	CeraOne Abutment System	Nobelphama
510(k) K944964	MirusCone Abutment System	Nobel Biocare
510(k) K961728	MirusCone Abutment System	Nobel Biocare
510(k) K971706	TiAdapt Abutment System	Nobel Biocare

5. Technological characteristics, comparison to predicate device.

The Promimic device is designed according to the long recognised principles of Professor Per-Ingvar Brånemark. The two-part titanium implant with a screw-shaped cylindrical fixture was introduced into clinical practice in 1965 and is at present commercially available in a large number of varieties provided by a large number of manufacturers. It is fair to state that this kind of implant has reached the status of a generic commodity.

The Promimic Dental Implants are manufactured by machining unalloyed titanium grade 4. This material has a long record as a standard material for surgical implants. The surfaces of the implantable parts are prepared by turning and milling, and the fixture surface is, in addition, subjected to a chemical process designed to yield a controlled surface chemistry, consisting out of hydroxyapatite crystals.

Characteristic	Promimic Dental Implant	Replus Dental Implants (HA) IMPLANT DIRECT LLC	NanoTite Dental Implants, Biomet 3I	BRÅNEMARK SYSTEM STANDARD · 3.75MM FIXTURE, NOBELPHARMA USA, INC.	ASTRA TECH IMPLANTS - DENTAL SYSTEM: NEW FIXTURES (MICROMACRO) , ASTRA TECH	SE
Indication for use	Surgical placement into upper/lower jaw arches as permanent support for prosthetic attachment, to restore masticatory function.	Surgical placement into upper/lower jaw arches as permanent support for prosthetic attachment, to restore masticatory function.	Surgical placement into upper/lower jaw arches as permanent support for prosthetic attachment, to restore masticatory function.	Surgical placement into upper/lower jaw arches as permanent support for prosthetic attachment, to restore masticatory function.	Surgical placement into upper/lower jaw arches as permanent support for prosthetic attachment, to restore masticatory function.	Yes
Dimensions	Diam. 3.75 mm length 8,5 – 15 mm	Diam. 3.7-5.7 mm, length 8-16 mm	Diam. 3.25-6 mm Length 8.5 -18 mm	Diam. 3.3, 3.75, 4,0, 5.0 mm Length 7, 10, 13, 15 mm	Diam. 3.5 and 4.0 mm Length 8-19 mm	Yes
Material	Commercially pure Titanium	Ti alloy grade 5	Ti alloy grade 5	Cp titanium	Cp titanium	Yes

Threaded	Yes	Yes	Yes	Yes	Yes	Yes
Surface	Spin coated nanometer scale HA	Plasma sprayed HA	A nanometer-scale discrete crystalline deposition (DCD™) of calcium phosphate (CaP)	Anodized Ti	Ti blasted	Yes
Surgical Technique	One – two stage	One- two stage	One- two stage	One- two stage	One- two stage	Yes
Sterilization Method	Radiation	Radiation	Radiation	Radiation	Radiation	Yes
Abutment connection	External hex,	Internal trilobe	External hex, and internal connection	External hex,	Conical internal	Yes
Abutment screw	M2	-tri rex I!L55	M2 for 3,75 mm implants	M2 for Regular platform implant	N/A	Yes
510(k)	**No number yet**	**K073161**	**K062432**	**K925765**	**K991053**	

6. Discussion of performance testing.

Promimic has used the guideline "Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments, dated May 12, 2004" regarding which test that should be performed regarding mechanical testing. As fatigue test are not performed on the implants they should not be used with angulated abutments. The Promimic Dental Implants are only to be used with straight abutments.

The mechanical properties and performed mechanical testing of the Promimic Dental Implant are in accordance to the above mentioned guideline and the system is generic to predicated previously marketed similar system. We have therefore come to the conclusion that additional testing would not raise issues of new or unidentified issues that would raise additional questions of safety and efficacy.

7. Conclusion

Based on comparison to the predicate device, ***Promimic Dental Implant*** is substantially equivalent to previously cleared predicate systems and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Karin Breding
Promimic AB
Stena Center 1B
SE-41292 Goteborg
Sweden

JAN 25 2011

Re: K101225
Trade/Device Name: Promimic AB, Promimic Dental Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant and Abutment
Regulatory Class: II
Product Code: DZE
Dated: January 21, 2011
Received: January 24, 2011

Dear Ms. Breding:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE

510(k) Number K101225

Device Name: Promimic AB, ***Promimic Dental Implant.***

Indications for Use:

The Promimic AB, Promimic Dental Implant is intended for surgical placement into the bone of upper/ lower jaw arches as a permanent anchorage for prosthetic devices and to restore chewing function. The Promimic Dental Implant can be immediately loaded only with good primary stability and appropriate occlusal loading. The Promimic Dental Implants are only to be used with straight abutments.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101225